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December 9, 2016

Ms. Kelly Sherman
Branch Chief, Risk Management and Implementation Branch III
Pesticide Re-Evaluation Division
Office of Pesticides Programs
United States Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: Malathion Registration Review and Endangered Species Evaluations

Dear Ms. Sherman:

FMC Corporation (EPA Company No.: 279) and Cheminova A/S (EPA Company No: 4787) are submitting three copies of the following document for consideration during the Agency's registration review and endangered species evaluations of malathion:

- 50133301** • Breton et al, 2016. Screening Level and Refined Ecological Risk Assessment of Malathion under FIFRA. Analyses and Report prepared by Intrinsik Environmental Sciences and Stone Environmental, Inc. Final Report dated December 1, 2016. Volumes 1-3. 1516 pp.

During its registration review of malathion, the Agency has decided not to issue the standard ecological risk assessment that it has historically produced to support decisions during reviews conducted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)¹. Instead, the Agency has stated that it intends to rely upon the biological evaluation (BE) that it is conducting using a new interim approach for evaluating potential effects under the Endangered Species Act (ESA) to cover the ecological risk evaluation under FIFRA.

¹ EPA continues to conduct and issue its standard ecological evaluations for other pesticides that it reviews during initial registration considerations, label expansions, and other pesticides undergoing registration review. Thus, the Agency is not treating all pesticides equally in carrying out its obligations under FIFRA.

FMC and Cheminova have concerns with EPA's decision not to produce a standard FIFRA ecological risk assessment for malathion. As noted in our joint statement with DAS and ADAMA², we have serious concerns about the process under which the draft BEs were prepared. And, for all of the reasons included in that statement, and in our comments on the draft BE for malathion³, we believe EPA's draft BEs fall far short of being scientifically defensible. Furthermore, the draft BE did not provide a basis for determining which of the individual use patterns for malathion could potentially result in exposures of concern or the probability of that exposure exceeding the Agency's level of concern for non-listed or listed species. As such, the BE provides no basis for determining where risk mitigation could be considered or should be focused, or for applying risk/benefit balancing under FIFRA.

With this in mind, we commissioned Intrinsik Environmental Science, Inc., and Stone Environmental, Inc., to conduct a Screening-Level-Ecological Risk Assessment and a refined ecological risk assessment that corrects many of the deficiencies that we observed in the draft BE. The results of these assessments are provided in this report. We believe that this assessment, including the data and tools used, represent the "best available data and science" with respect to assessing ecological risks to non-listed and listed species potentially exposed to malathion. Including a similar assessment as part of the early steps of the interim ESA evaluation process could have saved the Agency valuable time and resources in evaluating malathion under the ESA since it properly focuses the assessment on taxa that need a more refined analysis to determine the probability of adverse effects occurring.

We look forward to engaging with EPA on the issues raised in our comments on the draft BE for malathion and the ecological risks of malathion in general. As noted, we are submitting this report for the Agency's consideration in both its registration and endangered species reviews of Malathion, and ask that it be placed in all relevant dockets pertaining to these reviews.

² Joint Statement of DOW AgroSciences, LLC., Makteshim Agan of North America, Inc. ("ADAMA"), FMC Corporation (FMC) and Cheminova A/S (Cheminova) on the Policy Lessons to be Drawn from the Draft Biological Evaluations, June 10, 2016. Submitted to the docket on our behalf by David B. Weinberg, Wiley Rein LLP.

³ Breton, R.; Aslund, M.; Rodney, S.; et al. (2016) Response to EPA's Draft Biological Evaluation for Malathion. Final Report. Project Number: 60335. Unpublished study prepared by Intrinsik Environmental Sciences (US) Inc., Stone Environmental, Inc. 472p. EPA MRID 49949501.

If you have any questions or need additional information, please do not hesitate to contact me at 703-373-8885.

Sincerely,



Paul Whatling
Senior Registration Manager
FMC Corporation
EPA Agent for Cheminova A/S

Enclosure

- c. Steven Snyderman, EPA Chemical Review Manager for Malathion
Kristian Lystbæk, Cheminova A/S
John Cummings, FMC Corporation
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